K052806 1 OF 3

OCT 17 2005

WaveLight®

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Contact Person:	Alexander Popp Am Wolfsmantel 5 91058 Erlangen Germany Telephone: +49 (0)9131-6186-121 Fax: +49 (0)9131-6186-202
Summary Preparation Date:	July 30, 2004

2. **Names**

Device Name:	BURANE
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. **Predicate Devices**

The BURANE laser system is substantially equivalent to the Aesculap-Meditec MCL 29 Dermablate Laser System (K992707 and K964128), the Dornier Medilas E Laser (K981438), the Cynosure CO3 Er:YAG Laser (K983034), the Laserscope Laser VELA (K971843), the WaveLight BURANE XL (K050317) and the Sciton Er:YAG Laser PROFILE 3000 (K040005).

4. **Device Description**

BURANE is a Er:YAG laser system for dermatological interventions and for aesthetic laser applications. The BURANE has an *Ablation Mode* and a *Coagulation Mode*.

Furthermore, the laser system enables a quick, precise ablation with minimal thermal tissue damage. Thus an optimal wound healing process is achieved – the risk of scar formation is minimized. This is due to the BURANE's wavelength of 2.94 µm, which has an absorption maximum in water and is therefore absorbed very well by tissue water. The thermal damage zone is thus minimized.

While the parameter wavelength is specified by the device, spot size, laser energy, pulse sequence, and coagulation function can be selected by the treating physician for optimal adjustment to individual requirements.

5. Indications for Use

The BURANE is indicated:

The BURANE is intended to be used in small and large joint arthroscopy, laparoscopic procedures, general and all surgical procedures for incision/excision, vaporization, ablation, and coagulation of soft tissue and cartilage. All soft tissues encountered in all surgical procedures are included in this indication such as, skin, cutaneous tissue, subcutaneous tissue, straited and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The BURANE is indicated for use in skin resurfacing. The BURANE is indicated for use in medicine and surgery, in the following medical specialities: Dermatology, Plastic Gastroenterology, ENT, Thoracic Surgery, Oral & Maxillofacial Surgery, Ophtalmology & Podiatry.

Aesthetic Surgery
Skin resurfacing and treatment of wrinkles.

Dermatology/Plastic Surgery
Indications include, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitis ulcers.

Gastroenterology

General Surgery
The Er:YAG laser is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation.

WaveLight®

Genitourinary
Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminate, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Gynecology
Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

ENT
Indications include ear, nose and throat lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

Oral/Maxillofacial
Indications include benign oral tumors, oral and glossal lesions and gingivectomy.

Ophtalmology
Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Podiatry
Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

6. **Performance Data**
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Wavelight Laser Technologie AG
c/o Jeffrey D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K052806
Trade/Device Name: BURANE
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 29, 2005
Received: October 4, 2005

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052806 1 of 2

WaveLight®

510 (k) Indications for Use

Indications for Use

510(k) Number (if known): N/A
Device Name: BURANE

Indications for Use:

The BURANE is intended to be used in small and large joint arthroscopy, laparoscopic procedures, general and all surgical procedures for incision/excision, vaporization, ablation, and coagulation of soft tissue and cartilage. All soft tissues encountered in all surgical procedures are included in this indication such as, skin, cutaneous tissue, subcutaneous tissue, straited and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The BURANE is indicated for use in skin resurfacing. The BURANE is indicated for use in medicine and surgery, in the following medical specialities: Dermatology, Plastic Gastroenterology, ENT, Thoracic Surgery, Oral & Maxillofacial Surgery, Ophtalmology & Podiatry.

Aesthetic Surgery
Skin resurfacing and treatment of wrinkles.

Dermatology/Plastic Surgery
Indications include, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitis ulcers.

Gastroenterology

General Surgery
The Er:YAG laser is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation.

Genitourinary
Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminate, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Gynecology
Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page _1_ of _2_
(indication for use only)

0031

510(k) Number K052806

K052806 2 of 2

WaveLight®

510 (k) Indications for Use

ENT
Indications include ear, nose and throat lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

Oral/Maxillofacial
Indications include benign oral tumors, oral and glossal lesions and gingivectomy.

Ophtalmology
Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Podiatry
Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___N/A___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page _2_ of _2_
(indication for use only

510(k) Number K052806

0032